

## REMARKS

The claims have been amended to correct inadvertent errors and to clarify the scope of the invention under 35 U.S.C. § 112. No reduction in the scope of the claims, either express or implied, is intended, and no reduction of the scope of the claims should be inferred.

In the Office Action of January 8, 2003, the Examiner rejected claims 8-10 under 35 U.S.C. § 112, first paragraph, for failing to meet the written description requirement and for anticipation under 35 U.S.C. § 102(e) in light of U.S. Patent No. 6,024,981 to Khankari et al. ("Khankari"). Claims 11-15 were rejected as anticipated under 35 U.S.C. § 102(b) in light of U.K. Patent No. 2,307,857 to Leslie et al. ("Leslie"). Applicant respectfully traverses the Examiner's rejections, especially as related to the amended claims set forth herein, and requests allowance of the claims.

### 1. Written Description

The Examiner rejected claims 8-10 under the written description requirement. To support the rejection, the Examiner should "provide reasons why persons skilled in the art at the time the application was filed would not have recognized the description of this limitation in the disclosure of the application as filed." Manual of Patent Examining Procedure ("M.P.E.P.") § 2163.04 (a)(2).

The Examiner's argued that the words "substantially throughout" and "substantial constituent" were not disclosed in the specification, and the term "substantial[ly]" was undefined.

The Examiner's rejection is respectfully traversed. The written description standard requires "reasonable clarity," M.P.E.P. § 2163, in a specification that "reasonably conveys," M.P.E.P. § 2163.02, to the artisan that the inventor had possession of the subject matter when the application was filed.

Claim 8 has four elements: (1) a CO<sub>2</sub> donor, (2) an acidic component, (3) a pharmaceutically active substance, and (4) an "ingredient." Items (1) and (2) together comprise an effervescent couple. One advantage of the invention resides in forming a melt to isolate one or both members of the effervescent couple from the other and, optionally, the other formulation constituents. (Claim 8 has been amended to include language emphasizing this feature of the invention.) Claim 8 further defines the relationship of these four elements so that either the CO<sub>2</sub> donor or the acidic component (or both) is dispersed in a substrate comprising the ingredient. It is this substrate that forms the melt with one or both members of the effervescent couple. The substrate may comprise more than the "ingredient," and the claimed medicament may also contain more "ingredient" than is found in the substrate. The words "substantially throughout" are intended to convey to one skilled in the art that one or both of the effervescent couple should be sufficiently dispersed in the substrate to stabilize the medicament. The words

“substantial constituent” are intended to convey to one skilled in the art that the ingredient should comprise a sufficient amount of the substrate to stabilize the medicament.

Applicant is not seeking to extend the scope of the claims beyond permissible limits. The weight ranges of the ingredients of the claims are set forth at page 4, lines 25-35. The specification states that a process in which a preparation component is melted can increase the stability of effervescent preparations. (Page 1, lines 35-37). The materials that melt *at least partially* to form the melt (page 4, lines 1-15, emphasis added) need not melt totally. Any dispersion formed may have regions that are not perfectly homogenous, and, as set forth in claim 8, some part of the ingredient may not comprise a melted substrate. The specification points out that the melt can be produced in virtually any suitable manner (page 5, line 13) and under variable conditions. (Page 5, lines 13-25).

The description of the process is sufficient to convey to one of ordinary skill in the art that the inventors had the invention in hand at the time the application was filed. The fact that “substantial” and “substantially” are not rigidly defined in the specification is not important. “The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.” M.P.E.P. § 2163.02.

Applicant therefore requests that the Examiner withdraw this rejection and allow amended claim 8 and dependent claims 9 and 10.

2. Khankari

The Examiner had rejected claims 8-10, citing Example 1 and column 14, lines 44-65 of Khankari. The Examiner pointed out that claims 8-10 did not require a melt, so applicant's arguments in the preliminary amendment were not applicable. Applicant has revised claim 8 to emphasize the nature of the dispersion and to make the claim more clear to the Examiner. Applicant has, for the sake of clarity, described the structure using the term "melting." Applicant has not, however, surrendered techniques other than melting which may give a similar structure as required by claim 8.

The structure defined in claim 8 distinguishes the claimed invention from the Khankari structure. Khankari is directed to a quick-dissolve tablet. The relatively low compression strength of the Kahnkari tablet (20-50N) does not form a melt of a fusible sugar, sugar alcohol or sugar substitute sufficient to form the structure of claim 8.

3. Leslie

In the Office Action, the Examiner rejected the process claims under 35 U.S.C. § 102 (b), over Leslie. The Examiner argued that an effervescent couple, an active agent and a sweetener are disclosed in Leslie as well as granulation and extrusion. The

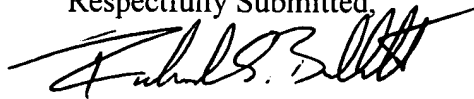
Examiner pointed out that claim 11 did not require that the at least partially melted ingredient be present in an amount sufficient to stabilize the dispersed member(s) of the effervescent couple.

This argument is respectfully traversed. Claim 11 has been amended to emphasize that the melt contains an amount of ingredient sufficient to stabilize the member(s) of the effervescent couple. Applicant's arguments with respect to Leslie, set forth in the preliminary amendment, are incorporated herein by reference. Withdrawal of the rejection is earnestly solicited.

#### Conclusion

In view of the arguments set forth above and the claim amendments presented herein, Applicants respectfully submit that the pending claims are in condition for allowance. Reconsideration is respectfully requested. The Examiner is invited to call the undersigned attorney at (973) 408-8229 with any questions.

Respectfully Submitted,



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